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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,399	07/22/2002	Takanori Kamada	10921.118USWO	4956
7590 05/12/2006		EXAMINER		
Hamre, Schumann, Mueller & Larson, P.C.		LUDLOW, JAN M		
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Minneapolis, MN 55402		PAPER NUMBER		

1743

DATE MAILED: 05/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/089,399

Applicant(s)

KAMADA ET AL.

Examiner

Jan M. Ludlow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-16 and 18-20 is/are pending in the application.
- 4a) Of the above claim(s) 4,5,8,10,18 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-9,13-16 and 18-20 is/are rejected.
- 7) ☒ Claim(s) 11 and 12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 July 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/28/2002</u> . | 6) <input type="checkbox"/> Other: _____ |

1. Claims 4-5, 8, 10, 18-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 12, 2005.
2. Claims 13-16, 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claim 13 is unclear because it is incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: there is no connection between the column and detector, or between the supply and discharge paths and any other element. Claim 14 is unclear as a whole because it is an apparatus claim, but recites only method steps. What structural features, such as sample injector, source of eluent, and/or eluent pump, is applicant trying to claim? The method of preparing the sample and the content of the sample are not seen as limiting the apparatus. Claim 15 is unclear as a whole because it is an apparatus claim, but recites only method steps. Further, the analyte is not a positively recited element of the invention and thus it is unclear how the limitation to the analyte limits the apparatus.
4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-2, 6-7, 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Hrdina (3520517).

Hrdina teaches a chromatographic flow cell having supply flow path 17, discharge flow path 18, a first intermediate flow path at the end of path 17 (comprising the taper and smaller diameter section), and second intermediate flow path between 17 and 18 as shown in Figures 4a-4b, corresponding to bore 2 of Figure 1. The first intermediate flow path is tapered, smaller than the other flow paths, and offset from the axis of cylindrical (Fig. 4b) second intermediate flow path. With respect to claim 6, Hrdina teaches that supply flow path 17 is a needle, the end of which may be tapered and narrowed (the tapered and narrow portion being the instant first intermediate path). It is the examiner's position that a needle so formed inherently has a second section of uniform cross section as shown in Figure 4b and as claimed. The flow paths are "integral" in that they are fixed in the cell..

9. Alternatively, claims 1-2, 6-7, 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hrdina.

Hrdina fails to teach that the flow paths are integral to the cell.

It would have been obvious to make the flow paths integral to the cell because "it is not invention either to make integral, parts that have formerly been distinct, or to separate two elements that formerly were integral." See:

THE CLEVELAND PUNCH & SHEAR WORKS CO. v. E. W. BLISS COMPANY et al.; S

AME v. MARQUETTE TOOL & MANUFACTURING CO.; E. W. BLISS COMPANY et al
. v. THE CLEVELAND PUNCH & SHEAR WORKS CO., 64 USPQ 77 (CA 6 1944).

10. Claims 13-16, 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hrdina as applied to claims above, and further in view of JP or Sugiyama.

Hrdina fails to teach the chromatographic system.

JP and Sugiyama each teach the chromatographic system as claimed (Fig. 1).

JP 11-166886 (hereafter "JP") teaches a chromatographic flow cell having a supply flow path 112, discharge flow path 116, a first intermediate flow path 120 and second intermediate flow path 114. The first intermediate flow path 120 intersects the second intermediate flow path 114 throughout a portion of the diameter of path 114 (see, e.g., Fig. 3), and therefore intersects at positions both aligned with and offset from the central axis of second intermediate flow path 114. Specifically, the center line of path 120 is offset from the central axis of path 114, and the depth (cross section) of path 120 is smaller than the diameter of 114, 112 and 116 as shown. A chromatographic system as claimed is shown in Figure 1. With respect to claims 14-15, it is the examiner's position that the apparatus of JP is structurally capable of the intended use recited.

Sugiyama (6122049) teaches a chromatographic flow cell having a supply flow path 112, discharge flow path 116, a first intermediate flow path 120 and second intermediate flow path 114. The first intermediate flow path 120 intersects the second intermediate flow path 114 throughout a portion of the diameter of path 114 (see, e.g., Fig. 3), and therefore intersects at positions both aligned with and offset from the central

axis of second intermediate flow path 114. Specifically, the center line of path 120 is offset from the central axis of path 114, and the depth (cross section) of path 120 is smaller than the diameter of 114, 112 and 116 as shown. A chromatographic system as claimed is shown in Figure 1. With respect to claims 14-15, it is the examiner's position that the apparatus of JP is structurally capable of the intended use recited.

It would have been obvious to provide the flow cell of Hrdina in the chromatographic system of JP or Sugiyama in order to use the flow cell for its stated intended use in a chromatographic system. With respect to claims 14-15, it is the examiner's position that the apparatus of JP is structurally capable of the intended use recited.

11. Claims 11-12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

12. The following is a statement of reasons for the indication of allowable subject matter: Hrdina does not teach or suggest the structure as claimed.

13. Applicant's arguments filed March 1, 2006 have been fully considered but they are not persuasive.

14. Claim 13 still does not recite structural relationships—compare to claim 1 in which communication of the flow paths is claimed. Claims 14-15 do not describe structural properties—for example, in claim 14, is a supply of sample claimed? a supply of eluent? a supply of diluent? any structure for combining the sample and diluent so as to dilute the sample? Pumps for supplying sample and eluant? Not as written—the

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claim recites, e.g., the method of diluting the sample, which has nothing to do with the structure of the apparatus, since such a step can be performed by hand prior to supplying the sample to the apparatus.

15. The rejections over JP and Sugiyama are overcome.

16. Applicant argues that Hrdina does not teach the supply and discharge paths formed integrally in the cell, but the needles are integral in that they are fixed in the cell. Note that the cell is made of plural parts, i.e., parts 14, 15, 16, 17, 18, and parts 18 and 19 are integral in that they are "essential or necessary for completeness" giving "integral" its broadest reasonable interpretation. Further, each needle fits in a bore drilled in a portion of the cell body 16. The examiner notes that the instant invention also includes ports for the insertion of tubing as shown in instant Figure 3. Further, even if the flow paths were not considered integral, it would have been obvious to make them integral in accordance with the case law cited above.

17. Applicant argues that Hrdina does not teach an eddy current generating path as claimed, but Hrdina clearly shows the tapered end of 17 intersecting the large detection chamber between windows 14 and 16 and generating an eddy (circular flow shown by arrows) in Figures 4a-4b.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (571) 272-1260. The examiner can normally be reached on Monday-Thursday, 11:30 am - 8:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jan M. Ludlow
Primary Examiner
Art Unit 1743

Jml

May 9, 2006